

## RFA 10-03: CIRM Targeted Clinical Development Awards Application Instructions

### RFA 10-03: Application Instructions

#### Application Requirements

1. **You will need a fully functional copy of Adobe Acrobat version 8 or 9 (Standard or Professional) to complete, print, and save the Information Form of the application.** For optimal performance, we recommend that you upgrade to Adobe Acrobat (Standard or Professional) version 8.1. Using Adobe Acrobat Reader will not permit you to save information that is entered in the form.
2. All application materials must be received by CIRM both electronically and in hard copy no later than **5:00pm PST on December 1st, 2010. Meeting this deadline is the applicant's responsibility, and no exceptions will be made.**
3. Applications will only be accepted from applicants that submitted an LOI that was accepted by CIRM. The Principal Investigator, Co-Principal Investigator (if applicable), and the clinical development project proposed in the application must be the same as those described in the LOI; otherwise, the application is deemed ineligible.
4. A complete application includes the following five parts and subparts:
  1. Part A: Application Information Form [PDF form]
    - i. Part A subpart I (if Co-PI) [PDF form]
  2. Part B: Targeted Clinical Development Proposal [MS Word template]
    - i. Part B subpart I: Clinical Protocol Synopsis/Synopses [included in Part B MS Word template]
    - ii. Part B subpart II: Manufacturing Plan Synopsis [included in Part B MS Word template]
    - iii. Part B subpart III: Activity Based Budget [MS Excel template]
  3. Part C: Biographical Sketches for Key Personnel and letters of collaboration [MS Word template]
  4. **Part D: Reference Materials (including Investigator Brochure) [PDF format]**
  5. Part E: Related Business Entities Disclosure Form [PDF form]
5. You must download and save a copy of the templates for the application onto your computer. **Do not open the documents directly from the CIRM web page, as the forms will not function properly.** Open and use the saved copies on your computer instead. You will need to download the Application Information Form (Part A) and Part A subpart I (if Co-PI); the Targeted Clinical Development Awards Proposal template (Part B) which includes Part B subparts I and II; the Activity Based budget (Part B subpart III, provided as a separate MS Excel template); the Biographical Sketches for Key Personnel template (Part C), and the Related Business Entities Disclosure Form (Part E).
6. **You must submit ALL application materials electronically** as instructed below. In addition, please submit **an original signed hardcopy of Parts A, B, C and E, plus 5 copies, preferably double-sided. Please do NOT submit hard copies of Part D (Reference Materials).** The original hard copy must be signed by the applicant (Principal Investigator) and the applicant institution's Authorized Organizational Official (AOO). The AOO is the individual, named by the applicant organization, who is authorized to act for the applicant organization and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to grant applications or grant awards. CIRM will not accept an application without these original signatures.
7. Written assurances of institutional approval for use of human subjects, covered stem cell lines, or vertebrate animals (where applicable) are not required at the time of application submission but will be required prior to issuance of Notice of Grant Award.

#### How to Apply

1. Download and save onto your computer a copy of the templates for the **Application Information Form** (Part A) and **subpart I** (if Co-PI); **Targeted Clinical Development Awards Proposal** (Part B) which includes Part B subparts I and II; **Activity Based budget** (Part B subpart III) provided as a separate MS Excel template; **Biographical Sketches for Key Personnel** (Part C), and **Related Business Entities Disclosure Form** (Part E).
2. Complete, save, and print the **Application Information Form** (Part A) and **subpart I** (if applicable) with Signature Page using the template provided. Be sure to provide all required information and observe indicated character limits.
3. Complete, save, and print the **Targeted Clinical Development Awards Proposal** (Part B) which includes subparts I and II, using the template provided. The proposal may include tables and figures. CIRM will not accept pages that exceed the indicated page limit for each section. We recommend that you convert the document into a PDF file to ensure that figures, tables, and formatting are preserved for submission to CIRM.

4. Complete, save, and print the **Activity Based Budget** (Part B subpart III) using the template provided. Note that the template contains 6 tabs in addition to the Instructions tab. Tabs 2, 4 and 6 **MUST** be completed; Tabs 3 and 5 should be completed only if applicable. Please provide all of the required information.
5. Use the templates provided to complete **Biographical Sketches for Key Personnel** (Part C). All biosketches should be assembled into a single document observing the two page limit per individual. We recommend that you convert the final document into a PDF file to ensure that formatting is preserved.
6. Complete, save, and print the Related Business Entities Disclosure Form (Part E). **Note that every applicant, whether from a for-profit or non-profit organization, must complete and submit this form.**
7. Please convert all reference materials (Part D) into PDF files for electronic submission. Do not submit hard copies of the reference materials.
8. Submit an electronic copy of **all five parts** of the application using the **Grants Management Portal** at:  
[https://grants.cirm.ca.gov/login/upgrade\\_browser](https://grants.cirm.ca.gov/login/upgrade_browser)
9. In addition to the electronic submission, submit an original hard copy plus 5 copies, of the completed Parts A, B, C and E of the application, signed by both the PI and the applicant institution's AOO, to the address below.
10. All application materials as described above must be received by CIRM both electronically and in hard copy **no later than 5:00pm PST, December 1st, 2010. Meeting this deadline is the applicant's responsibility, and no exceptions will be made.** You will receive an email reply confirming receipt of your proposal by CIRM.

**Mail the completed original hard copy plus 5 copies (preferably double-sided) to:**

Targeted Clinical Development Awards Application  
California Institute for Regenerative Medicine  
210 King Street  
San Francisco, CA 94107

## **Contact Information**

### **For information about this RFA**

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### **For information about the review process:**

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